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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/125,031	03/10/1999	SHIRLEY LONGACRE-ANDRE	0660-0139-0X	7351

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02/26/2002

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EXAMINER

GRUN, JAMES LESLIE

ART UNIT	PAPER NUMBER
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1641

25

DATE MAILED: 02/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/125,031

Applicant(s)
LONGACRE-ANDRE et al.

Examiner
James L. Grun, Ph.D.

Art Unit
1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 Dec 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-53, 55-63, and 65-68 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 68 is/are allowed.
- 6) ☒ Claim(s) 46-53, 55-63, 65, and 66 is/are rejected.
- 7) ☒ Claim(s) 67 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The amendment filed 10 December 2001 is acknowledged and has been entered. Claims 46-53, 55-63, and 65-68 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant is now required to submit acceptable drawings within the time period set in the Office action. See 37 CFR 1.85(a). Submission of acceptable drawings may no longer be held in abeyance pending the indication of allowable subject matter. Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

The specification is objected to and claims 56-63 are rejected under 35 U.S.C. 112, first paragraph, for the reasons of record that the specification, although enabling for particular constructs as found in the deposited viruses given CNCM registration numbers I-1659, I-1660, I-1661, I-1662, and I-1663, does not reasonably provide description or enablement for an invention of the scope as instantly claimed, particularly wherein those N-terminal *Plasmodium* MSP-1 signal peptide-encoding sequences critical or essential to the practice of the invention are not included in the claims.

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Applicant's arguments filed 10 December 2001 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's argument to the contrary, the claims have not been amended as asserted and the rejection is maintained for reasons of record.

Claims 56-63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Although describing, and being enabling for, particular constructs as found in the deposited viruses given CNCM registration numbers I-1659, I-1660, I-1661, I-1662, and I-1663, the specification does not reasonably provide description of or enablement for an invention of the scope as instantly claimed because one would not know, absent further description and guidance from applicant, what sequences or characteristics are intended as encompassed by a "gene." There is no accepted definition of the term in the art or provided in the specification such that one would readily know or be able to predict or envision what structure is encompassed within the metes and bounds of the invention as claimed. For example if a gene is defined as that sequence as found in the genome, applicant's specification does not describe and enable any "gene" as instantly claimed because applicant clearly teaches that the native coding sequence of

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the *P. falciparum* MSP-1 protein has a G + C content of 33%. Thus, one would be unable to envision, obtain, or make any "gene" as defined above as instantly claimed. Moreover, the gene sequence as found in the genome may include introns and specific splice donor/acceptor sequences which are not disclosed by the description merely of an encoding sequence. Absent any written description of those essential elements encompassed by the term "gene," one would be unable to envision, obtain, or predictably make any "gene" as instantly claimed.

Claims 46-53 and 55-63 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 46-53, the interrelationships of the components are not clear. The following is again suggested: --60%, and a polynucleotide--.

In claim 55, it is believed that --I-1663-- was intended.

In claims 56-63, it is not clear what is encompassed by a "gene" as the art and the specification do not provide an accepted definition thereof.

Applicant's arguments filed 10 December 2001 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertion to the contrary, claims 46-53 have not been amended as suggested by the examiner and the rejection of these claims is maintained as set forth above.

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Claims 46, 48, 56, 58, 61, and 65-66 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Chappel et al (Mol. Biochem. Parasitol. 60:303, 1993), Miller et al (Mol. Biochem. Parasitol. 59:1, 1993), and Longacre et al (Mol. Biochem. Parasitol. 64:191, 1994), for reasons of record

Applicant's arguments filed 10 December 2001 have been fully considered but they are not deemed to be persuasive.

Applicant again urges that the declaration of Dr. Longacre-Andre under 37 CFR § 1.132, filed 03 August 2000, provides sufficient evidence of unobvious and unpredictable advantages to overcome the rejection. This is not found persuasive as the showing in the declaration is incommensurate in scope with the invention as claimed in the instantly rejected claims. As set forth, the known sequence of the antigenic C-terminal fragment of the *P. falciparum* MSP-1 protein would have made obvious to one of ordinary skill in the art the genus of encoding polynucleotides and one of such ordinary skill would have expected many polynucleotides of the genus specifically encoding this known sequence to function in baculovirus vectors for protein fragment expression as taught in the combined references, particularly in view of the successful expression of the antigenic C-terminal fragment of the *P. falciparum* MSP-1 protein in a baculovirus vector as taught in Chappel et al. Again, it is not clear that the range of total G+C alone can be used as predictive of an unobvious enhanced expression in a baculovirus vector, as the specific sequence shown to be expressed by applicant was apparently modified based upon preferred codon usage in Sf9 cells and not merely upon G+C content.

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Applicant urges that the references do not teach or provide motivation for altering the GC content of the nucleotide sequence of the *P. falciparum* MSP-1 encoding sequence. This is not found persuasive because, as set forth, one would have expected many polynucleotides of the genus specifically encoding the known sequence of the antigenic *P. falciparum* MSP-1 protein C-terminal p19 fragment to function in baculovirus vectors as taught by the combined references and would have had motivation to use any of the genus of encoding polynucleotides therefor.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant urges that Chappel et al do not teach a recombinant baculovirus vector expressing a C-terminal MSP-1 fragment. This is not found persuasive in view of the teachings of the reference as set forth. Applicant's attention is drawn to the relevant teachings of Chappel et al, e.g. in the section bridging pages 304-305 and in the legend of Fig.1C on page 305.

Claim 68 is currently allowable.

Claim 67 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

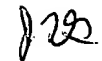
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (703) 308-3980. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (703) 305-3399.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306, or (703) 305-3014, or (703) 308-4242. Official After Final communications, only, can be facsimile transmitted to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. The above inquiries, or requests to supply missing elements from Office communications, can also be directed to the TC 1600 Customer Service Office at phone numbers (703) 308-0197 or (703) 308-0198.



James L. Grun, Ph.D.
February 24, 2002



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/641